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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,944

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Brian E. Jones

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EXAMINER

SWOPE, SHERIDAN

ART UNIT

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1652

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/549,944	Applicant(s) JONES ET AL.	
	Examiner SHERIDAN SWOPE	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 17-20, 22-24 and 30-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 16, 21 and 25-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>0707</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' election, with traverse, of Invention II(D) in their response of March 25, 2009 is acknowledged. The elected invention is directed to a Bacillus cellulase polypeptide. Applicants' traversal is based on the argument that all claims embody a special technical feature, a novel BagCel cellulase. This is not found to be persuasive because Claim 33 is rendered obvious by the prior art; see the restriction of March 25, 2009 and below.

Claims 1-33 are pending. Claims 1-14, 17-20, 22-24, and 30-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 15, 16, 21, and 25-29 are hereby examined.

Priority

The priority date granted for the elected invention is April 28, 2004, the filing date of PCT/US04/13175, which disclosed the recited invention. It is noted that US 60/467,255 does not disclose the genus of polypeptides having at least 85% identity with SEQ ID NO: 3 or the encoding polynucleotides thereof.

Information Disclosure Statement

Some references listed on the Information Disclosure Statement have not been considered because they have not been provided to the Examiner (see strikeouts). If Applicants wish for said references to be considered, a supplementary Information Disclosure Statement and the references should be filed. Any rejection based on said references will not be considered to be new grounds for rejection.

Specification-Objections

The first paragraph of the specification should be updated to reflect the current status of all US parent applications.

The specification is objected to for describing Figures 1-3, while no figures have been filed.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Utility

The specification teaches isolation of a polynucleotide encoding a protein having cellulase activity. The specification states: “The nucleotide sequence of this ORF is shown in FIG. 2. [0151]” and “The translated protein composed of 570 amino acids is shown in FIG. 3. [0154]”. However, there are no figures in the instant application. For purposes of examination, it is assumed that the figures disclosed in US 60/467,255 are meant to also be the figures of the instant application. Making said assumption, SEQ ID NO: 1 is the ORF shown in FIG. 2 and SEQ ID NO: 3 is the protein shown in FIG. 3. Based on said assumption, the polynucleotide of SEQ ID NO: 1 and the protein of SEQ ID NO: 3 have utility based on expression in heterologous cells and enzymatic analysis using carboxymethylcellulose (Examples 3-6).

Art Unit: 1652

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 16, 21, and 25-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

For Claims 15, 16, 21, and 25-29, the term “BagCel” renders the claim indefinite. Neither the specification, the claims, nor the prior art provide a definition of said term. The skilled artisan would not know the metes and bounds of the recited invention. For purposes of examination, it is assumed that “BagCel” means a Bacillus-derived cellulase.

Claims 15 and 25 are rendered indefinite by improper Markush language; an “and” is needed after 15d and 25d.

Claim 16 is confusing and indefinite; the skilled artisan would not know the metes and bounds of the recited invention.

Claim 21 is rendered indefinite by being dependent from a non-elected claim.

Claims 15, 16, 16, and 29 are rendered indefinite for improper antecedent usage as follows.

For Claim 15d and 25d, the phrase “an amino acid sequence presented in Figure 3 (SEQ ID NO:3)” should be corrected to “the amino acid sequence presented in Figure 3 (SEQ ID NO:3)”. Claim 29, as dependent from Claim 15, is indefinite for the same reason.

For Claim 16, “The substainially purified BagCel” lacks antecedent basis.

For Claims 26 and 29, the phrase “a cellulase according to Claim 15” should be corrected to “the cellulase according to Claim 15”.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 15, 16, 21, and 25-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptide of SEQ ID NO: 3, does not reasonably provide enablement for any protein comprising a polypeptide having at least 85% identity with SEQ ID NO: 3 or any protein encoded by any polynucleotide comprising a sequence having at least 85% identity with SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In regards to this enablement rejection, the application disclosure and claims are compared per the factors indicated in the decision *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill

Art Unit: 1652

of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claims 15, 16, 21, and 25-29 are so broad as to encompass any protein comprising a polypeptide having at least 85% identity with SEQ ID NO: 3 or any protein encoded by any polynucleotide comprising a sequence having at least 85% identity with SEQ ID NO: 1. It is noted that by use of “comprising” language, these claims encompass polypeptides, wherein the activity is not derived from the sequence homologous to SEQ ID NO: 3.

The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins broadly encompassed by the claim. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired cellulase activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of SEQ ID NO: 3 and the nucleotide sequence of SEQ ID NO: 1.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims. Furthermore, the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are unpredictable (Galyle et al, 1993;

Art Unit: 1652

Whisstock et al, 2003). In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of Claims 15, 16, 21, and 25-29, which encompasses all proteins comprising a polypeptide having at least 85% identity with SEQ ID NO: 3 or any protein encoded by any polynucleotide comprising a sequence having at least 85% identity with SEQ ID NO: 1. The specification does not support the broad scope of Claims 15, 16, 21, and 25-29 because the specification does not establish: (A) regions of the protein structure which may be modified without affecting the cellulase activity; (B) the general tolerance of the cellulase activity to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of proteins comprising a polypeptide with an enormous number of amino acid modifications of the polypeptide of SEQ ID NO: 3. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of proteins having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Written Description

Claims 15, 16, 21, and 25-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of proteins comprising a polypeptide having at least 85% identity with SEQ ID NO: 3 or any protein encoded by any polynucleotide comprising a sequence having at least 85% identity with SEQ ID NO: 1. The specification teaches the structure of only a single representative species of such proteins, the protein of SEQ ID NO: 1. The specification teaches the structure of no representative species of proteins comprising a sequence having at least 85% identity with SEQ ID NO: 3, wherein the cellulase activity is derived from the region not homologous to SEQ ID NO: 3. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of having cellulase activity. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1652

Claims 15, 16, 21, and 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulein et al, 1999. Schulein et al teach a Bacillus polypeptide having cellulase activity and having 94% identity with SEQ ID NO: 3. Schulein et al further teach the polynucleotide encoding their cellulase and a detergent composition comprising their protein. Therefore, Claims 15, 16, 21, and 25-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulein et al, 1999.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulein et al, 1999 in view of what was well-known in the art. The teachings of Schulein et al are described above. Schulein et al do not teach a feed additive comprising their cellulase. However, adding cellulases to feed was well-known in the art. It would have been obvious to a person of ordinary skill in the art to make and use a feed additive comprising the cellulase of Schulein et al. Motivation to do so is provided by the fact that cellulases aid in ruminant digestion of vegetative matter. The expectation of success is high, as adding cellulases to feed was well-known in the art. Therefore, Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulein et al, 1999 in view of what was well-known in the art.

Allowable Subject Matter

No claims are allowable.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is also requested that the serial number of the application be referenced on every page of the response.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652